REMARKS/ARGUMENTS

Claims 40-47 are currently pending in the application. Applicants have canceled claims 48-51. Applicants reserve the right to pursue the subject matter of these claims in a continuation application. Applicants have amended claims 40-42 and 44-46 to clarify the subject matter of the claims. No new matter has been added.

Error in Claim Listing

The Examiner indicated that the amendment to claim 41 in the previous response contained an error. Specifically, the phrase, "consisting of" between the phrase, "from the group" and the word "psoriasis" was added but not underlined. Applicants thank the Examiner for pointing out the error. Future claim amendments will comply with 37 C.F.R. § 1.121(c).

Claim Objections

Applicants acknowledge that claims 43, 47 and 51 stand objected to for depending from a rejected base claim, but would otherwise be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims. Applicants also note that claim 51 has been canceled, herein.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 48 and 51 under 35 U.S.C. § 112, second paragraph for indefiniteness. Applicants have canceled claims 48 and 51, rendering this rejection moot.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 40-42, 44-46 and 48-50 under 35 U.S.C. § 103 for obviousness over the teachings of Burchardt *et al.* WO 97/15298 ("Burchardt"). Applicants have canceled claims 48-50, rendering this rejection moot as it applies to these claims. The Examiner argued that Burchardt teaches the administration of a glucocorticosteroid and an LTD4 receptor antagonist for the treatment of a chronic inflammatory disorder, such as psoriasis. The Examiner further mentions that Burchardt lists carbenoxolone sodium as one of many glucocorticosteroids that could potentially be used. The Examiner argued, that while the claims encompass a method of using a pharmaceutical composition consisting only of carbenoxolone and a pharmaceutically

acceptable carrier, that the claims were still obvious over the teachings of Burchardt. The Examiner argued that the definition of pharmaceutically acceptable carrier in the specification was broad enough to cover an LTD4 receptor antagonist and that the Applicants had not provided any evidence that LTD4 would not be considered a pharmaceutically acceptable carrier, diluent or excipient by one of ordinary skill in the art. Thus, the Examiner argued that claims 40-42, 44-46 and 48-50 were obvious over the teachings of Burchardt. Applicants respectfully traverse.

Applicants have amended claim 40, from which the remaining claims depend, to recite that the pharmaceutical composition consists of carbenoxolone and one or more pharmaceutically acceptable excipients. Applicants also provide Remington: The Science and Practice of Pharmacy p. 741-742 (2006) ("Remington"), included herewith as Exhibit A. Pages 741-742 of Reminigton teach that excipients are needed, "to stabilize the API (active pharmaceutical ingredient) by providing antioxidant, heavy-metal chelating, or light protection properties. They also may be used to enhance bioavailability and to control the release from dosage forms."

Applicants also provide additional definitions from other sources. About.com defines pharmaceutical excipients as "pharmaceutical additives, the inactive ingredients used to make up a medication. They include dyes, flavors, binders, emollients, fillers, lubricants, preservatives, and many more classifications. Common excipients include cornstarch, lactose, talc, magnesium stearate, sucrose, gelatin, calcium stearate, silicon dioxide, shellac and glaze."[1] Pharmaceutical-technology.com defines pharmaceutical excipient as, "an inert substance, which is added to a drug to provide bulk, *e.g.* in tablets."[2] The definition of excipient in Pifferi and Restani, Il Farmico 58 (2003) 541-550 ("Pifferi"), included herewith as Exhibit D, is as an inert substance added to a prescription to confer a suitable consistency.[3]

Based on the above evidence, Applicants submit that one of ordinary skill in the art would not consider LTD4 receptor antagonist of Burchardt to be a pharmaceutically acceptable excipient, because it is not inert and does not stabilize, preserve or have any other pharmaceutically relevant effect on carbenoxolone. Applicants assert that based on this evidence, the Examiner has not provided a *prima facie* case of obviousness and respectfully requests that this rejection be withdrawn.

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[1] Web page as found on the Internet at http://bipolar.about.com/od/medications/g/gl_excipient.htm included herewith as Exhibit B.

[2] Web page as found on the Internet at http://www.pharmaceutical-technology.com/glossary/excipient.html included herewith as Exhibit C.

CONCLUSION

Applicants respectfully request prompt examination in the application. If there are any questions regarding this Response, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

/Sean M. Coughlin/

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[3] *See* Pifferi at 541.